

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC.,)
)
Plaintiff,)
)
v.) C.A. No. 21-1286 (MSG)
) C.A. No. 21-1455 (MSG)
BIONPHARMA INC.,)
)
Defendant.)

**PLAINTIFF AZURITY PHARMACEUTICALS, INC.'S
OPENING BRIEF IN SUPPORT OF PLAINTIFF'S MOTION TO DISMISS
DEFENDANT BIONPHARMA INC.'S COUNTERCLAIMS OR,
IN THE ALTERNATIVE, TO BIFURCATE AND STAY THEM**

OF COUNSEL:

Wendy L. Devine
Kristina M. Hanson
Nicholas Halkowski
WILSON SONSINI GOODRICH & ROSATI
One Market Plaza
Spear Tower, Suite 3300
San Francisco, CA 94105
(415) 947-2000

Natalie J. Morgan
Evan Sumner
WILSON SONSINI GOODRICH & ROSATI
12235 El Camino Real, Suite 200
San Diego, CA 92130-3002
(858) 350-2300

MORRIS, NICHOLS, ARSH & TUNNELL LLP
Jack B. Blumenfeld (#1014)
Megan E. Dellinger (#5739)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
mdellinger@morrisnichols.com

*Attorneys for Plaintiff Azurity
Pharmaceuticals, Inc.*

Ty W. Callahan
Granville C. Kaufman
WILSON SONSINI GOODRICH & ROSATI
633 West Fifth Street, Suite 1550
Los Angeles, CA 90071
(323) 210-2900

Jeffrey C. Bank
Alexander Poonai
WILSON SONSINI GOODRICH & ROSATI
1700 K Street NW, Fifth Floor
Washington, DC 20006
(202) 973-8800

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TABLE OF ABBREVIATIONS

Abbreviation	Description (Date of Issuance for Patents)
'008 Patent	U.S. Patent No. 9,669,008 (Jun. 6, 2017)
'745 Patent	U.S. Patent No. 10,039,745 (Aug. 7, 2018)
'442 Patent	U.S. Patent No. 9,808,442 (Nov. 7, 2017)
'987 Patent	U.S. Patent No. 10,154,987 (Dec. 18, 2018)
First Patents	'008 Patent, '745 Patent, '442 Patent, and '987 Patent
First Suits	18-1962 and 19-1067 (D. Del.)
'868 Patent	U.S. Patent No. 10,772,868 (Sept. 15, 2020)
'482 Patent	U.S. Patent No. 10,786,482 (Sept. 29, 2020)
Second Patents	'868 Patent and '482 Patent
Second Suits	20-1256 (D. Del.)
'023 Patent	U.S. Patent No. 11,040,023 (Jun. 22, 2021)
'405 Patent	U.S. Patent No. 11,141,405 (Oct. 12, 2021)
Third Patents	'023 Patent and '405 Patent
Third Suits	21-1286 and 21-1455 (D. Del.)
Azurity	Plaintiff Azurity Pharmaceuticals, Inc. (formerly known as Silvergate Pharmaceuticals, Inc.)
Bionpharma or Bion	Defendant Bionpharma Inc.
CoreRx	Non-party CoreRx, Inc.
Epaned®	The enalapril product that is the subject of Azurity's NDA No. 208686
FDA	U.S. Food & Drug Administration
The Hatch-Waxman Act	Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984
NDA	New Drug Application
ANDA	Abbreviated New Drug Application
POSA	Person of Ordinary Skill in the Art
USPTO	United States Patent and Trademark Office
DOE	Doctrine of equivalents

** All citations and internal quotations omitted and emphasis added unless otherwise noted.

I. NATURE & STAGE OF THE PROCEEDINGS

Azurity filed complaints against Bionpharma (“Bion”) for infringement of the ’023 and ’405 Patents under 35 U.S.C. § 271(e)(2). D.I. 1; 21-1455 D.I. 1. Bion filed a motion to dismiss, which was denied. D.I. 8, 87. After Bion launched its product, Azurity amended its complaint to include infringement counts pursuant to 35 U.S.C. § 271(a)-(c) and a jury demand. D.I. 89. Bion filed a second motion to dismiss, which was also denied. D.I. 97, 124. For both complaints, Bion filed substantively identical counterclaims, Counts III and IV (the “Antitrust Counterclaims”). D.I. 135; 21-1455 D.I. 46. Azurity now moves to dismiss the Antitrust Counterclaims.¹

II. INTRODUCTION AND SUMMARY OF THE ARGUMENT

Pursuant to Fed. R. Civ. P. 12(b)(6), Azurity respectfully requests an order dismissing the Antitrust Counterclaims for failure to state a claim on which relief can be granted. In the alternative, Azurity respectfully requests that the Court bifurcate the Antitrust Counterclaims and stay them pending resolution of the patent claims.

Bion’s Antitrust Counterclaims boil down to a narrow—and untenable—proposition: that Azurity allegedly violated the antitrust laws by initiating “sham” litigation to protect its intellectual property relating to Epaned®. The bar for sham litigation is very high, particularly in the Hatch-Waxman context, and Bion falls far short. As an initial matter, Count III is barred because Bion claims that Azurity engaged in alleged sham litigation in a *previous, separate* litigation, and that claim must have been brought in that litigation, not this one. Regardless, both of the Antitrust Counterclaims fail because Azurity’s suits are immune from antitrust liability under the *Noerr Pennington* doctrine². As the Third Circuit has held, brand drug manufacturers like Azurity

¹ Defendant’s Counterclaims are nearly identical in substance, with the addition of seven paragraphs directed at the ’405 patent in C.A. No. 21-1455. For simplicity, citations herein are made to the C.A. No. 21-1286 Counterclaims, unless otherwise noted.

² *E.R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965).

should not be “penalize[d]” for pursuing litigation against potential generic entrants where their “litigiousness was a product of Hatch-Waxman,” as it was here. *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 147-48, 158 (3d Cir. 2017). Finally, even if it could overcome Azurity’s immunity, Bion fails to adequately plead the necessary elements of an antitrust claim, including causation and injury. Accordingly, Bion’s Antitrust Counterclaims should be dismissed.

III. STATEMENT OF FACTS

A. Statutory Framework

The Hatch-Waxman Act establishes procedures that incentivize the development of new drugs, facilitate competition from generic drugs, and set forth how and when the innovator company may sue the potential generic company for infringement. *See* D.I. 135, ¶¶ 28-31. Innovator companies, like Azurity, list in the FDA-published “Orange Book” certain patents associated with the brand drug. *Id.*, ¶ 31. Patents are presumed valid after they are issued by the USPTO. 35 U.S.C. § 282(a). A company seeking to market a generic version of the brand drug may rely on the innovator’s research and clinical data (D.I. 135, ¶ 30), but for each listed patent, it must make one of four possible certifications as to whether the potential generic is barred by that patent. *Id.*, ¶ 31. Pertinent to this case is a “Paragraph IV” certification that the patent is purportedly invalid or will not be infringed by the generic drug. *Id.*

When an ANDA applicant makes a Paragraph IV Certification, the Hatch-Waxman Act enables the NDA holder to dispute the Certification and bring a patent infringement lawsuit. *Id.*, ¶ 32. After the NDA holder files suit, the FDA may not grant final approval to the ANDA applicant until either thirty months have passed (“30-month stay”) or until a court rules in favor of the ANDA applicant as to noninfringement or invalidity. *Id.* Under this framework, the NDA holder has “an extremely limited time, just 45 days, in which to decide whether (and, if so, where and against

whom), to file suit, if it is to obtain the benefit of the automatic stay of FDA approval.” *Belcher Pharm., LLC v. Int’l Medication Sys., Ltd.*, 379 F.Supp.3d 326, 331 (D. Del. 2019) (Stark, J.).

B. Azurity and Epaned®

Azurity is a small innovator pharmaceutical company that invented Epaned®, a revolutionary ready-to-use oral formulation of the blood pressure medication enalapril, used by vulnerable pediatric and elderly patients with heart and blood pressure issues. No viable ready-to-use oral liquid formulation existed prior to Azurity’s development of Epaned®, and prior liquid formulations suffered from compliance and stability issues. D.I. 135, ¶¶ 198-200. Epaned® resolved those issues, and on September 20, 2016, the FDA approved Azurity’s NDA. *Id.*, ¶ 34.

The USPTO granted Azurity a number of patents covering its groundbreaking invention. The first was the ’008 Patent, which issued on June 6, 2017 and which covered ready-to-use enalapril formulations that were more easily administrable to pediatric and elderly patients. *Id.*, ¶¶ 198-199. The USPTO then granted three additional patents: the ’442 Patent on November 7, 2017, the ’745 Patent on August 7, 2018, and the ’987 Patent on December 18, 2018, all of which became the subject of the first infringement litigation between Azurity and Bion. *Id.*, ¶ 56. Later, the USPTO granted Azurity additional patents, including those at issue in this litigation.

C. The Bion Patent Litigation Suits and Bion’s Launch

On October 30, 2018, Bion notified Azurity that it was seeking approval to market a generic version of Epaned® and included a Paragraph IV Certification as to the patents Azurity had listed in the Orange Book at the time. D.I. 135, ¶ 64. Under the Hatch-Waxman Act, Azurity then had 45 days to file an infringement lawsuit. During that time, the parties could not reach a confidentiality agreement, and Bion refused to allow Azurity to examine its ANDA. *Id.*, ¶¶ 66, 69. Regardless, Bion’s Paragraph IV Certification alone constitutes an act of infringement (35 U.S.C. § 271(e)(2)), and Azurity followed the procedure set forth in the Hatch-Waxman Act by filing suit.

1. First Suits (D. Del.: 18-1962, 19-1067)

Azurity sued Bion for infringement of the '008, '745, and '442 Patents on December 1, 2018, and infringement of the later-issued '987 Patent on June 7, 2019. *Silvergate Pharm. Inc. v. Bionpharma, Inc.*, No. 18-1962 (D. Del.), D.I. 1; No. 19-1067 (D. Del.), D.I. 1.³ Bion moved for leave to file a motion for judgment on the pleadings, arguing that it did not infringe the asserted claims literally or under the doctrine of equivalents. *Silvergate*, No. 18-1962, D.I. 57, 58. This Court denied Bion's request, explaining that it could not resolve many of the complex issues without the aid of expert discovery. Ex. 1 at 68:19-70:19 ("All I can say today is this case does not fall into the category where it's clear to me today that I could and should resolve the disputes the defendants want me to resolve at this stage of the case prior to trial and prior to hearing from witnesses, including particularly expert witnesses."). Bion did not move for summary judgment.

At trial, the parties introduced multiple witnesses and hundreds of exhibits. *Silvergate*, No. 18-1962, D.I. 211 at 1 n.1. Almost three months after trial, on April 27, 2021, the Court ultimately decided in Bion's favor, issuing a 70-page opinion. *Id.*, D.I. 307. On March 9, 2022, the Federal Circuit affirmed the district court decision with no opinion. *Azurity Pharm., Inc. v. Bionpharma Inc.*, Nos. 21-1926, 21-1927, D.I. 48 (Fed. Cir.).

Bion never asserted an antitrust counterclaim in the First Suit.

2. Second Suits (D. Del.: 20-1256)

While the First Patent Litigation was pending, the USPTO issued additional patents to Azurity covering the novel enalapril formulations. Azurity sued Bion on the Second Patents, but

³ On a motion to dismiss, courts may consider the complaint's allegations and exhibits and matters of public record including court dockets. Courts may also consider documents "integral to or explicitly relied upon in the complaint ... without converting the motion to dismiss into one for summary judgment." *Doe v. Univ. of the Scis.*, 961 F.3d 203, 208 (3d Cir. 2020).

later agreed to dismiss the claims based on the Court’s rulings in the First Suits. *Silverbate Pharm., Inc. v. Bionpharma Inc.*, No. 20-1256 (D. Del.), D.I. 106 (May 17, 2021).

3. Third Suits (D. Del.: 21-1286, 21-1455)

The USPTO issued the ’023 Patent on June 22, 2021 and the ’405 Patent on October 12, 2021. Exs. 2, 3. Unlike the First Patents, the ’023 Patent does not require (but allows for) a buffer. *See, e.g.*, Ex. 2 at Claim 1. The ’405 Patent contains similar claims to the ’023 Patent, but allows for a wider variety of preservatives and allows for an optional buffer in some claims. *See, e.g.*, Ex. 3 at Claim 1, Claim 13. Azurity sued Bion for infringement of the ’023 Patent on June 22, 2021 (D.I. 1), and the ’405 Patent on October 15, 2021 (*Azurity Pharm., Inc. v. Bionpharma Inc.*, 21-1455 (D. Del.), D.I. 1). Bion again sought early dismissal of Azurity’s claims, and again the Court rejected its motions. D.I. 98, 124; *see also* 21-1455 (D. Del.), D.I. 13, 35.

4. Bion’s Delayed Launch and CoreRx

Bion received tentative approval from the FDA for its ANDA on December 28, 2020. D.I. 135, ¶ 189. The Court in the First Suits entered a final judgment in Bion’s favor on April 29, 2021, but the FDA did not grant final approval until August 10, 2021, and Bion waited until August 17, 2021 to launch. *Id.*, ¶ 139.

Bion’s generic product is supplied by CoreRx, a contract manufacturer. *Id.*, ¶ 15. Based on CoreRx manufacturing Bion’s allegedly infringing product at issue in this litigation, Azurity also sued CoreRx for infringement of the ’023 and ’405 Patents. *Azurity Pharm., Inc. v. CoreRx, Inc.*, No. 21-2515 (M.D. Fla.); *Azurity Pharm., Inc. v. CoreRx, Inc.*, No. 21-1522 (D. Del.) (collectively, the “CoreRx Suits”). CoreRx settled with Azurity to avoid the risk of being “put … out of business” if found liable for willful infringement. D.I. 135, ¶ 157 (citing *Bionpharma v. CoreRx, Inc.*, No. 21-10656 (JGK) (S.D.N.Y.), D.I. 56 at 26:20-28:14 (attached hereto as Ex. 4)).

5. Bion's Antitrust Counterclaims

Bion asserts two claims under the Sherman Act. In Count III (alleged monopolization), Bion alleges that Azurity's Hatch-Waxman litigation on the First Patents was a sham. D.I. 135, ¶¶ 236-244. That purportedly sham litigation—in which the Court denied Bion's motion for leave to file a motion for judgment on the pleadings—allegedly resulted in damages relating to the delay of Bion's product launch. *Id.*, ¶ 220-221. Bion does not allege that this litigation, 21-1286, is relevant to Count III.

In Count IV (alleged attempted monopolization), Bion alleges that Azurity filed other so-called sham litigations, including this litigation and the CoreRx Suits. *Id.*, ¶¶ 245-252. Regarding this litigation, Bion alleges it is a “sham” because the Third Patents are purportedly “invalid” (*id.*, ¶ 171), but Bion’s allegations that the patent was “mistakenly” issued, although wrong, are directed at the USPTO, not Azurity. *Id.*, ¶ 133 (“because of the Examiner’s mistaken belief … the ’023 patent issued”), 21-1455 D.I. 46, ¶ 138 (“because of the Examiner’s mistaken belief … the ’405 patent issued”). Bion advises that it will assert supposedly unassailable defenses based on an alleged license and patent exhaustion, D.I. 135, ¶ 242, but Bion has stated that its defenses will require extensive discovery. D.I. 101.

Regarding the CoreRx Suits, Bion alleges that because Azurity and CoreRx are portfolio companies owned by a private equity fund (NovaQuest), they supposedly cannot have adverse legal interests, which would make the Suits a sham. *Id.*, ¶ 150. However, Bion does not allege any facts showing that Azurity or NovaQuest controlled CoreRx with respect to its litigation strategy or manufacturing relationship with Bion.

Bion alleges no delay or lost profits in Count IV (nor could it, since it has been selling its generic enalapril product since August 17, 2021 and continues to do so today), nor does it provide

any factual allegations as to the alleged “competitive harm” that would ensue as a result of the litigations. *Id.*, ¶¶ 250-251.

IV. ARGUMENT

To survive a Rule 12(b)(6) motion to dismiss, a counterclaim must “state a claim [for] relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). To do so, the counterclaim must contain enough factual allegations to “permit the court to infer more than the mere possibility of misconduct.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Mere “[t]hreadbare recitals of the elements of a cause of action” and “conclusory statements” will not suffice. *Id.*

A. Count III Is Barred Because It Was a Compulsory Counterclaim

Sham litigation claims must be brought in the litigation on which they are premised. Count III, which is solely based on the patents at issue in a different litigation than this one, is barred because Bion did not assert this compulsory claim in the First Suits. Bion states that its claim exclusively derives from Azurity’s “filing and prosecution of the [alleged] sham First Wave Suits” and the purported “actual and proximate cause of the loss and injury” was “Azurity’s conduct in instituting and prosecuting the [alleged] sham First Wave Suits.” D.I. 135, ¶¶ 240-242. The facts alleged in support of Count III were known to Bion during the First Suits, and Bion’s failure to assert this claim in the First Suits is fatal to its current pleading.

A counterclaim is compulsory if it “arises out of the [same] transaction or occurrence that is the subject matter of the opposing party’s claim.” Fed. R. Civ. P. 13(a)(1)(A). “[T]he relevant inquiry is whether the counterclaim ‘bears a logical relationship to an opposing party’s claim.’” *Transamerica Occidental Life Ins. Co. v. Aviation Office of Am., Inc.*, 292 F.3d 384, 389 (3d Cir. 2002) (quoting *Xerox Corp. v. SCM Corp.*, 576 F.2d 1057, 1059 (3d Cir. 1978)). To promote judicial economy, the concept of “logical relationship” is construed liberally. *Id.* Failure to assert

a compulsory counterclaim in the same suit bars the counterclaimant from asserting it in a later suit. *M.R. v. Ridley Sch. Dist.*, 744 F.3d 112, 121 (3d Cir. 2014). Such is the case here.

In infringement litigation, a sham claim is a compulsory counterclaim that must be raised during the allegedly sham suit. *Medical Mut. of Ohio, Inc. v. Braintree Labs.*, No. 10-604-SLR, 2011 WL 2708818, at *4 & n.9 (D. Del. July 12, 2011) (“Had [plaintiff] not pled sham litigation as a counterclaim in the original action, the claim could not have been raised in a subsequent suit.”); *U.S. Philips Corp. v. Sears Roebuck & Co.*, 55 F.3d 592, 597 (Fed. Cir. 1995) (“[T]he place to challenge litigation as sham is in the asserted sham litigation . . .”); *see also Rohm & Haas Co. v. Brotech Corp.*, 770 F. Supp. 928, 933 (D. Del. 1991) (barring antitrust claim because “the later filed antitrust [claim is] logically related to the patent claims at issue in the earlier filed suit”).

Here, Bion did not assert its antitrust claim at any stage of the First Suits. *Silvergate*, No. 18-1962, D.I. 7 (May 6, 2019); No. 19-1067, D.I. 24 (Dec. 17, 2019). Instead, it waited until over three years after Azurity filed the earliest First Suits on December 12, 2018, over a year after Bion received tentative approval for its ANDA on December 28, 2020, and a year after trial on the First Suits ended. D.I. 135, ¶¶ 72, 189. Unlike patent misuse claims, which may be permissive in very narrow circumstances where the claim is not logically connected to the initial infringement action *see Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 671 (1944), Bion’s claim entirely hinges on its assertion that a previous, separate litigation was allegedly a sham. *See, e.g.*, D.I. 135, ¶¶ 240-243. As a result, Bion is barred from asserting this claim now.

B. *Noerr-Pennington* Bars the Antitrust Counterclaims

Noerr-Pennington demands dismissal of both Counts III and IV because the First Amendment protects Azurity’s right “to petition the Government for a redress of grievances” as “immune from antitrust liability.” *BE&K Constr. Co. v. NLRB*, 536 U.S. 516, 524-526 (2002). The

Third Circuit has explained that a party “claiming that a lawsuit is, by its very existence, anticompetitive and unlawful faces an uphill battle.” *In re Wellbutrin*, 868 F.3d at 147.

It is especially difficult for a claimant to plausibly plead sham litigation in ANDA cases, such as this one, because of the need to respect congressional policy. *Id.* at 158 (declining to “penalize a brand-name manufacturer whose ‘litigiousness was a product of Hatch-Waxman’” and stating that “[d]oing so would punish behavior that Congress sought to encourage.”); *La. Health. Serv. & Indem. Co. v. Janssen Biotech, Inc.*, No. 19-cv-14146, 2021 WL 4988523, at *7 (D.N.J. Oct. 27, 2021) (granting a motion to dismiss a sham litigation claim and noting, “[i]n the Hatch-Waxman context, [Noerr-Pennington] means that antitrust liability will usually not attach to a patentee who sues generic manufacturers after receiving a Paragraph IV notice letter...”).

In order to overcome *Noerr-Pennington* immunity, a plaintiff must meet a narrow exception showing that the challenged lawsuit in question is “a mere sham to cover … an attempt to interfere directly with the business relationships of a competitor.” *Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc.*, (“PRE”) 508 U.S. 49, 51 (1993). The sham exception to the *Noerr-Pennington* immunity has two parts. First, the plaintiff must show that the challenged lawsuit was “objectively baseless.” *Id.* at 60. Second, the plaintiff must challenge the defendant’s “subjective motivation” for bringing the suit. *Id.* A court may only consider the second prong if it first concludes that the suit was objectively baseless. *Id.* Although some courts have held that a “holistic” approach is appropriate where serial petitioning is alleged, that approach is not applicable where the defendant engaged in only a small number of litigations, particularly in the Hatch-Waxman context. *In re Wellbutrin*, 868 F.3d at 157-58 (rejecting serial petitioning charge where litigant only pursued two proceedings and noting that the Hatch-Waxman Act procedures

explain multiple filings by brand drug manufacturers). Even if a claimant can satisfy both prongs, it must also plausibly plead the substantive elements of an antitrust claim. *PRE*, 508 US at 60-61.

A lawsuit is “objectively baseless” only if “no reasonable litigant could realistically expect success on the merits.” *Id.* at 60. If a plaintiff had “probable cause to institute legal proceedings,” the litigation was not a sham. *Id.* at 62. Probable cause requires “no more than a reasonable belief that there is a chance that a claim may be held valid upon adjudication.” *Id.* at 62-63. Critically, “the essential question is not whether the suit succeeds, but whether the suit was a sham at the time it was filed.” *In re Wellbutrin*, 868 F. 3d at 148-49 (citing *PRE*, 508 U.S. at 60).

“Under the subjective motivation prong, a plaintiff must show that the defendant ‘brought baseless claims in an attempt to thwart competition (*i.e.*, in bad faith).’” *FTC v. AbbVie*, 976 F.3d 327, 360 (3d. Cir. 2020), *cert. denied*, 141 S. Ct. 2838 (2021). Courts will consider whether the defendant was “indifferent to the outcome on the merits,” whether damages would be too low to justify investment in the suit, and whether the defendant “decided to sue primarily for the benefit of collateral injuries inflicted through the use of legal process.” *Id.* at 370. However, in the Hatch-Waxman context, it is insufficient for a plaintiff to merely show that “the patentee harbors the anticompetitive motive to delay generic competition.” *La. Health Serv.*, 2021 WL 4988523 at *7.

1. Count III: The First Suits

a. Azurity Had Probable Cause to Litigate and Expect Success

Bion’s claim fails because it has not pled (and cannot plead) facts showing that no reasonable litigant could have expected to succeed on the First Patents and because Azurity was justified in bringing suit based on Bion’s Paragraph IV Certification. The Counterclaims focus extensively on relitigating the merits of the First Suits, which misses the point. The question under *Noerr-Pennington* is not whether Azurity ultimately prevailed or if it prioritized arguments during the litigation as discovery sharpened the issues (as would be expected). Rather, the pertinent

question is whether Azurity had probable cause to bring the litigation in the first place. *In re Wellbutrin*, 868 F.3d at 148-49. Here, it did. Bion’s bare non-infringement positions in its Paragraph IV Certification were unsupported and unsubstantiated, and Bion provided no basis for challenging the validity of the patent. D.I. 135, ¶ 64. Accordingly, a reasonable litigant would have had probable cause to bring the First Suits, thereby precluding a finding that they were objectively baseless. See *In re Wellbutrin*, 868 F.3d at 149 (“Since the submission of an ANDA is, by statutory definition, an infringing act, an infringement suit filed in response to an ANDA with a paragraph IV certification could only be objectively baseless if no reasonable person could disagree with the assertions of noninfringement or invalidity in the certification.”); *AstraZeneca AB v. Mylan Labs. Inc.*, No. 00-cv-6749, 2010 WL 2079722, at *4 (S.D.N.Y. May 19, 2010) (finding objectively reasonable basis to sue because the generic “provided [defendant] notice of its Paragraph IV certification”).

Even if one were to examine the extensive litigation history, it is clear that the First Suits were not so lopsided to be a sham; indeed, Azurity’s belief that it was going to succeed is reflected in many of the Court’s rulings. The Court refused to grant a motion for *leave to file a motion* for judgment on the pleadings, noting that Bion had essentially already briefed the merits of such a motion and that the Court did not think it would be successful. Ex. 1 at 68:19-70:19. Subsequently, the Court required substantial expert evidence from both sides for a multi-day trial (D.I. 135, ¶ 93), and authored an over 70-page opinion setting forth findings of fact and conclusions of law. *Silvergate*, 18-1962, D.I. 307; see *La. Health Serv.*, 2021 WL 4988523 at *9 (finding that similar indicators demonstrated that a litigation was not objectively baseless); *AstraZeneca AB*, 2010 WL 2079722 at *4 (same). Nor did Bion think of its case as unassailable because even after extensive discovery, Bion did not seek leave to file a summary judgment motion. *AstraZeneca AB*, 2010 WL

2079722 at *4 (“surviving summary judgment … provides strong evidence that [the defendant] could have reasonably expected success on the merits.”). On appeal, “[t]he Federal Circuit heard oral argument, indicating that the panel did not unanimously view the appeal as frivolous.” *Amgen Inc. v. Coherus Biosciences, Inc.*, No. 17-546-LPS, 2020 WL 7024872 at *4 (D. Del. Nov. 30, 2020) (Stark, J.).

Against those realities, Bion cannot now claim that Azurity lacked any reasonable basis to bring a suit in the first place. Although some of Bion’s defenses eventually found success, it is bedrock law that Azurity’s loss is insufficient to conclude the litigation was a sham. *PRE*, 508 U.S. at 60, n.5 (“a court must resist the … temptation to engage in *post hoc* reasoning by concluding that an ultimately unsuccessful action must have been unreasonable or without foundation.”).

Regardless, Bion’s *post hoc* re-telling of the First Suits does not plausibly plead sham. With respect to the first limitation, Bion now alleges that Azurity’s preservative argument was so meritless as to constitute a sham because Azurity was supposedly barred from asserting DOE under the disclosure-dedication doctrine. D.I. 135, ¶ 79. But the bar for invoking that doctrine requires showing a very detailed level of specificity in the disclosure and the alleged disclosure must be presented “as an alternative” to the claimed limitation. *SanDisk Corp. v. Kingston Tech. Co.*, 695 F.3d 1348, 1363-64 (Fed. Cir. 2012). Here, Azurity had disclosed parabens, but it had *not* expressly listed a mixture of the two parabens in Bion’s product “as an alternative” to the sodium benzoate. No. 18-1962, D.I. 192, at 19. Accordingly, a reasonable litigant could have realistically expected to succeed, and in fact the Court acknowledged that expert discovery was necessary to assess the merits of the claim. Ex. 1 at 71:1-4.

Similarly, Bion’s buffer defenses were far from guaranteed. Azurity’s argument against amendment-based estoppel was not “frivolous” (D.I. 135, ¶¶ 85-86), because Azurity believed the

amendment was made for clarification purposes and was not a narrowing amendment. *Silverage*, 18-1962, D.I. 206 at 10 (March 5, 2021); *see Honeywell Int'l, Inc. v. Hamilton Sundstrand Corp.*, 378 F. Supp. 2d 459, 474 (D. Del. 2005). Bion also faced a high bar on argument-based estoppel, and Azurity's argument that the prosecution history failed to "evince a clear and unmistakable surrender of subject matter" because it did not "explicitly disavow a specific feature in the prior art." *See Intendis GmbH v. Glenmark Pharm. Inc.*, 822 F.3d 1355, 1365 (Fed. Cir. 2016); *Baseball Quick, LLC v. MLB Advanced Media L.P.*, No. 11-cv-1735, 2014 WL 6850965, at *9 (S.D.N.Y. Dec. 4, 2014).

b. Azurity's Subjective Intent Was To Defend Its Rights and Comply with the Hatch-Waxman Act

Because Bion has not plausibly pled that the First Suits were objectively baseless at the time of filing, this Court need not consider the subjective prong of the sham litigation test. *See Sections IV.B.1.a, supra; PRE*, 508 U.S. at 60. Regardless, Bion has failed to meet its burden on this prong as well. First, Bion alleges that Azurity filed the First Suits "for the purpose of securing the automatic 30-month stay" (D.I. 135, ¶ 163), but this charge merely restates the procedure under the Hatch-Waxman Act. The stay is automatic and is binding on the FDA. *See* 21 U.S.C. § 355(j)(5)(B)(iii). As required by law, Azurity listed the presumptively-valid First Patents in the Orange Book. Bion filed an ANDA with a Paragraph IV Certification, which constitutes an act of infringement giving rise to Azurity's litigation. 35 U.S.C. § 271(e)(2). If Azurity were only interested in the stay, as Bion claims, it would not have spent resources pursuing the appeal, especially after the stay expired and Bion launched.

Next, Bion alleges that the First Suits provided Azurity time to file additional patents. D.I. 135, ¶ 163. The act of filing the First Suits has no bearing on Azurity's patent prosecution. The 30-month stay prevents the FDA from approving an ANDA, but it has no effect on the

USPTO. Regardless of the First Suits or the 30-month stay, Azurity could have continued to pursue patent protection for its innovations as it is entitled to do. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Moreover, Bion’s unsupported accusation that the patents suffered from “obvious invalidity” fails to state a claim under *Iqbal*, and Bion cannot plead that any of the patents have ever been held invalid.

Finally, Bion mischaracterizes its OCA as including “reasonable confidentiality restrictions,” without detailing what these so-called “reasonable” restrictions were. D.I. 135, ¶ 65. Such conclusory allegations are insufficient (*Iqbal*, 556 U.S. at 678), and, moreover, courts recognize that deference to the patentee’s decision to sue is appropriate given the limited time period proscribed by the Hatch-Waxman Act. *Belcher Pharmas.*, 379 F. Supp. 3d at 331; *Celgene Corp. v. KV Pharm. Co.*, No. 07-4819, 2008 WL 2856469, at *3-4 (D.N.J. July 22, 2008).

2. Count IV: The Third Suits and the CoreRx Litigation

a. Azurity Had Probable Cause To Bring the Third Suits

Bion again fails to plausibly plead objective baselessness. To date, Bion has not put forth a substantive noninfringement position to the disputed claims. Instead, Bion argues the Third Suits are objectively baseless because Azurity knew or should have known that the relevant patents are invalid. D.I. 135, ¶ 144. Neither argument has merit.

With regards to Bion’s validity claims, it is undeniable that all issued patents are “presumed valid” and that, “[t]he presumption of validity includes a presumption that the patent complies with § 112.” *Nat’l Recovery Techs., Inc. v. Magnetic Separation Sys, Inc.*, 166 F.3d 1190, 1195 (Fed. Cir. 1999). At all times, “[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity,” *i.e.* on Bion. 35 U.S.C. § 282(a). “That presumption takes away any need for a plaintiff to prove his patent valid to bring a claim.” *Commil USA, LLC v. Cisco Sys.*, 575 U.S. 632, 643 (2015); *BASF Corp. v. SNF Holding Co.*, 955 F.3d

958, 963 (Fed. Cir. 2020). The crux of Bion’s invalidity argument appears to be the unsupported allegation that the USPTO made errors (D.I. 135, ¶¶ 133-38), but Azurity cannot be penalized for bringing this lawsuit exactly as the law proscribes. *In re Wellbutrin*, 868 F.3d at 158.

Bion fares no better with its claims that the litigation is objectively baseless because it claims to have a license to the patents-in-suit or that patent exhaustion applies. Bion pleads that it has a license to Azurity’s technology based on a supply agreement it entered into with CoreRx. D.I. 135, ¶ 136. Bion overstates its argument, which will require several (faulty) factual and legal leaps. To prevail as pleaded, Bion will have to show that Azurity essentially became a party to the manufacturing agreement signed between Bion and CoreRx despite never alleging that Azurity ever saw the agreement, let alone agreed to it. *Id.*, ¶¶ 25-26. Bion does not cite any language from the contract to support its legal conclusion. *Iqbal*, 556 U.S. at 678. Bion’s patent exhaustion argument is even more tenuous: it asserts that Azurity’s claims are barred because CoreRx manufactured Bion’s product, and CoreRx and Azurity now have a common investor. D.I. 135, ¶ 144. Bion relies only on conclusionary allegations, which fail to state a claim. *Iqbal*, 556 U.S. at 678. Neither of these positions merit dismissing the lawsuit now, let alone concluding that it is a sham.

b. The CoreRx Suits Were Not Objectively Baseless

Bion claims that the CoreRx Suits were objectively baseless because, according to Bion, Azurity and CoreRx cannot have “adverse legal interests” as portfolio companies of a single private equity fund. D.I. 135, ¶¶ 149-51, 176. Bion improperly conflates parent-subsidiary corporate relationships (where wholly owned subsidiaries may be considered a single entity, particularly in antitrust analysis) with portfolio company relationships (where two independently managed corporations may have a common investor). Bion’s position is contrary to caselaw, and, if adopted, would have far-reaching implications for private equity and corporate law.

Courts recognize the “presumption of corporate separateness,” which states that corporations are distinct from their corporate and non-corporate shareholders. *See, e.g., Wenske v. Blue Bell Creameries, Inc.*, No. 17-0699-JRS, 2018 WL 5994971, at *5 (Del. Ch. Nov. 13, 2018). This presumption exists even when “entities have identical officers and directors” (*id.*), or when they “are under common ownership and control.” *Allied Capital Corp. v. GC-Sun Holdings, L.P.*, 910 A.2d 1020, 1038 (Del. Ch. 2006). Bion fails to allege any facts (nor could it) showing that Azurity and CoreRx operate or are managed as a single entity, or that control was exerted over CoreRx in a way that would render the CoreRx Suits a sham. Additionally, Bion asserts that the purpose of the CoreRx Suits was to purportedly “paper over” CoreRx’s cessation of supply to Bion, but that does not make sense in light of Bion’s allegation that Azurity (or its private equity investor) could have simply “direct[ed] CoreRx to cease manufacturing for Bion without involving the courts.” D.I. 135, ¶ 150. *See also* Section IV. C *infra* (describing why Bion’s claim fails for lack of antitrust injury).

c. Azurity’s Subjective Intent Was To Defend Its Patents

Because Bion has not plausibly pled that either the Third Suits or the CoreRx Suits were objectively baseless at the time of filing, the Court need not consider the subjective prong of the sham litigation test. *See Sections IV. B.2.a and b, supra; PRE*, 508 U.S. at 60. Regardless, Bion fails on that prong too. Bion alleges that Azurity filed the Third Suits and the CoreRx Suits “not to obtain a judgment on the merits,” but instead to “coerce” Bion to stop selling its infringing product by burdening it with “the costs of patent litigation” and “to paper over CoreRx’s intended breach of its supply contract obligations to Bionpharma.” D.I. 135, ¶¶ 187-88. But Bion does not allege that the Third Patents have been declared invalid or unenforceable (indeed, none of the Epaned® patents have been declared invalid or unenforceable), and it does not allege the CoreRx could plausibly argue non-infringement. Nor has Bion alleged that Azurity’s enforcement of its

patent rights are somehow atypical of the approach taken by other innovators in the Hatch-Waxman framework. The reality is that Azurity's patents enjoy the presumption of validity, and Azurity's litigation strategy reflects a good faith effort to protect its intellectual property.

C. Bion Fails To Plead Certain Elements of an Antitrust Claim

Even if Bion succeeds under the sham litigation exception, it "must still prove a substantive antitrust violation." *In re Wellbutrin*, 868 F.3d at 149 (citing *PRE*, 508 U.S. at 61). Although Azurity is not challenging Bion's alleged relevant market definitions in this motion, it reserves the right to do so should the claims proceed. Regardless, Bion's claims fail on other grounds.

First, in Count III, Bion alleges that, but for Azurity's First Suits, Bion would have launched its product "no later than December 28, 2020, when Bion received tentative approval for its ANDA." D.I. 135, ¶ 189. It further asserts that, after that date, "the only barrier to final approval was the 30-month stay automatically triggered" by the First Suits. *Id.*, ¶ 218. However, Bion obtained a final judgment in the First Suits on April 29, 2021 and waited over three and a half months to launch its product on August 17, 2021. *Id.*, ¶¶ 98, 139. Bion claims that Azurity caused the delay until August (*id.*, ¶ 194), but it fails to allege how. Bion does not allege why it waited over three months to launch its product, why the FDA withheld final approval until August 10, 2021, or how the FDA's delay was caused by Azurity (nor could it). Nor does Bion allege why it waited a week after final approval to launch. Bion's own delay severs any causation between the First Suits and Bion's delayed entry after April 29, 2021, and it also fatally undermines their conclusory allegation that it would have launched on December 28, 2020, but for the lawsuit. The pleading offers no factual allegations as to how Bion would have obtained final approval then and whether and when it was commercially prepared to launch. Absent such allegations, Bion has failed to adequately plead causation and antitrust injury. *Twombly*, 550 at 555.

Second, Count IV fails because Bion does not and cannot plausibly allege antitrust injury that could flow from the alleged conduct supporting the attempted monopolization claim. If Azurity wins this litigation, it may lawfully exclude Bion, and if Azurity loses, then there is no exclusion. Similarly, the CoreRx Suits were settled, and CoreRx is still supplying Bion, so Bion fails to allege potential harm from those suits as well. Additionally, Bion alleges that, because Azurity and CoreRx are each portfolio companies of NovaQuest, “NovaQuest has the power to control them, and thus to direct CoreRx to cease manufacturing for Bion without involving the courts.” D.I. 135, ¶ 150. Thus, Bion alleges that NovaQuest could have simply “directed CoreRx to breach its supply contract with Bion without involving a court.” *Id.*, ¶ 188. Bion’s allegations sever their own causation. Either Bion is wrong, and the companies had adverse legal interests and the CoreRx Suits could not have been a sham. Or, if, as Bion alleges, Azurity could have simply ordered CoreRx to stop supplying Bion without the CoreRx Suits, then Bion’s result is the same under both scenarios: CoreRx would have stopped supplying Bion with the infringing product.⁴ Because Bion’s but-for world is the same as the real world, it cannot plead that its hypothetical “injuries” would flow from the alleged attempted monopolization. *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977).

Third, Bion fails to sufficiently allege a specific intent to monopolize. *Phila. Taxi. Ass’n, Inc. v. Uber Techs., Inc.*, 886 F.3d 332, 341 (3d Cir. 2018). Instead, Bion baldly asserts that “[u]pon information and belief, Azurity … has the specific intent to once again monopolize the Relevant Market” (D.I. 135, ¶ 249), but “pleading upon information and belief is permissible,” only when it is accompanied by factual allegations and not “‘boilerplate and conclusory allegations’” like

⁴ Whether the cessation of supply would have constituted a breach of contract is at issue in a separate litigation (*Bion Inc. v. CoreRx, Inc.*, No. 21-10656 (JGK) (S.D.N.Y.)), but it is a contractual law issue, not an antitrust issue.

those in the Counterclaims. *McDermott v. Clondalkin Grp., Inc.*, 649 F. App'x 263, 267-68 (3d. Cir. May 18, 2016) (quotation omitted). Furthermore, Bion's allegations amount to, at most, an intent to exclude infringing products, which is insufficient. *La. Health Serv.*, 2021 WL 4988523 at *7.

Fourth, Bion vaguely alleges that Azurity's Third Suits and CoreRx suits resulted in "attendant costs and disruption" (D.I. 135, ¶ 250), but it provides no factual allegations, and regardless, it launched and continues to sell its generic enalapril maleate oral solution product today without any factual allegations of anticompetitive harm caused by the lawsuits described in Count IV. See *Astrazeneca AB v. Glenmark Generics Ltd.*, No. 14-665-GMS, 2014 WL 5366050, at *1 n.1 (D. Del. Oct. 9, 2014) (granting motion to dismiss sham litigation claim and finding that fees to defend the litigation are "purely personal and cannot establish an antitrust injury"); *Otsuka Pharm. Co., Ltd. v. Torrent Pharm. Ltd., Inc.*, 187 F. Supp. 3d 483, 486-87 (D.N.J. 2016) (same).

V. BION'S COUNTERCLAIMS SHOULD BE STAYED

To the extent any survive, the Antitrust Counterclaims should be stayed pending resolution of the patent claims in this litigation. A district court may "order a separate trial of one or more separate issues, claims, cross-claims, counterclaims, or third-party claims," to promote "convenience, to avoid prejudice, or to expedite and economize." Fed. R. Civ. P. 42(b); *Eagle Pharm., Inc. v. Eli Lilly & Co.*, No. 18-1121-MSG, 2018 WL 6201704, at *2 n.3 (D. Del. Nov. 27, 2018) (Goldberg, J.) ("[I]t is common practice for courts to stay an antitrust case until after resolution of a related patent case.").

Four reasons support Azurity's position. *First*, resolution of the patent claims in Azurity's favor will moot Bion's antitrust claims. *Apotex, Inc. v. Senju Pharm. Co.*, 921 F. Supp. 2d 308, 314 (D. Del. 2013). *Second*, Bion concedes that antitrust discovery—largely concerning the merits of a litigation wholly separate from this one—will massively extend the timeline needed to resolve

this litigation. Indeed, that appears to be the driving force behind Bion’s claims: to extend this litigation so it may continue to enjoy unabated sales of its infringing product. The parties ought to focus on the merits of the claims related to the ’023 and ’405 Patents, not discovery related to numerous patents not at issue here. *Third*, “[t]here is a strong likelihood that consideration of the patent validity issues will be delayed significantly if tried together with the antitrust issues.” *Masimo Corp. v. Philips Elecs. N. Am. Corp.*, No. 09-80, 2010 WL 925864, at *2 (D. Del. Mar. 11, 2010). Because Bion is currently marketing an infringing product, delaying resolution of the infringement claims with antitrust discovery would provide Bion an unjustified “tactical advantage.” *Eagle Pharm.*, 2018 WL 6201704 at *2. *Fourth*, it would be untenable for a jury to consider the merits of Azurity’s patents in this case and simultaneously evaluate the merits of IP and antitrust claims based on different patents asserted in a different litigation. *Dentsply Int’l Inc. v. New Tech. Co.*, No. 96-272, 1996 WL 756766, at *5 (D. Del. Dec. 19, 1996) (avoiding jury confusion is the “primary end” to which Rule 42(b) orders to bifurcate are directed). Accordingly, bifurcation and a stay are justified.

VI. CONCLUSION

For the reasons stated above, Azurity respectfully requests that the Court grant its motion to dismiss, or in the alternative, that the Court bifurcate and stay the Antitrust Counterclaims.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Megan E. Dellinger

OF COUNSEL:

Wendy L. Devine
Kristina M. Hanson
Nicholas Halkowski
WILSON SONSINI GOODRICH & ROSATI
One Market Plaza
Spear Tower, Suite 3300
San Francisco, CA 94105
(415) 947-2000

Jack B. Blumenfeld (#1014)
Megan E. Dellinger (#5739)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
mdellinger@morrisnichols.com

*Attorneys for Plaintiff Azurity
Pharmaceuticals, Inc.*

Natalie J. Morgan
Evan Sumner
WILSON SONSINI GOODRICH & ROSATI
12235 El Camino Real, Suite 200
San Diego, CA 92130-3002
(858) 350-2300

Ty W. Callahan
Granville C. Kaufman
WILSON SONSINI GOODRICH & ROSATI
633 West Fifth Street, Suite 1550
Los Angeles, CA 90071
(323) 210-2900

Jeffrey C. Bank
Alexander Poonai
WILSON SONSINI GOODRICH & ROSATI
1700 K Street NW, Fifth Floor
Washington, DC 20006
(202) 973-8800

March 24, 2022

CERTIFICATE OF SERVICE

I hereby certify that on March 24, 2022 I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on March 24, 2022, upon the following in the manner indicated:

John C. Phillips, Jr., Esquire
Megan C. Haney, Esquire
PHILLIPS, MC LAUGHLIN & HALL, P.A.
1200 North Broom Street
Wilmington, DE 19806-4204
Attorneys for Defendant Bionpharma Inc.

VIA ELECTRONIC MAIL

Andrew M. Alul, Esquire
Roshan P. Shrestha, Esquire
TAFT STETTINIUS & HOLLISTER LLP
111 East Wacker Drive, Suite 2800
Chicago, IL 60601
Attorneys for Defendant Bionpharma Inc.

VIA ELECTRONIC MAIL

Aaron M. Johnson, Esquire
TAFT STETTINIUS & HOLLISTER LLP
2200 IDS Center
80 South Eighth Street
Minneapolis, MN 55402
Attorneys for Defendant Bionpharma Inc.

VIA ELECTRONIC MAIL

Christopher J. Kelly, Esquire
MAYER BROWN LLP
Two Palo Alto Square, Suite 300
3000 El Camino Real
Palo Alto, CA 94306
Attorneys for Defendant Bionpharma Inc.

VIA ELECTRONIC MAIL

/s/ *Megan E. Dellinger*

Megan E. Dellinger (#5739)